MAR 1 3 2014

510(k) Summary

MEDTRONIC Sofamor Danek

CAPSTONE PTC™ and CLYDESDALE PTC™ Spinal Systems

March 2014

I.	**Company:**	Medtronic Sofamor Danek, USA Inc. 1800 Pyramid Place Memphis, Tennessee 38132 (901) 396-3133
II.	**Contact:**	Julie Bassett Regulatory Affairs Program Manager Telephone: (901) 399-3248 Fax: (901) 346-9738
III.	**Proposed Proprietary Trade Name:**	CAPSTONE PTC™ Spinal System and CLYDESDALE PTC™ Spinal System
IV.	**Classification Names:**	Intervertebral Body Fusion Device (21 CFR 888.3080)
	Class:	II
	Product Code:	MAX

V. **Description:**

The CAPSTONE PTC™ and CLYDESDALE PTC™ Spinal Systems consist of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The CAPSTONE PTC™ and CLYDESDALE PTC™ Spinal Systems will be available in all the same sizes as the predicate systems.

VI. Indications for Use:

CAPSTONE PTC™ Spinal System:

The CAPSTONE PTC™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the CAPSTONE PTC™ Spinal System is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the Food and Drug Administration (FDA) for use in the lumbar spine.

CLYDESDALE PTC™ Spinal System:

CLYDESDALE PTC™ Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE PTC™ Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to

S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

VII. Summary of the Technological Characteristics:

The CAPSTONE PTC™ and CLYDESDALE PTC™ Spinal Systems have the same fundamental technology as the predicate CAPSTONE® and CLYDESDALE® Spinal Systems. The CAPSTONE PTC™ and CLYDESDALE PTC™ System implants (subject devices) and the CAPSTONE® and CLYDESDALE® Spinal System implants (predicate devices), are both made from PEEK material with tantalum markers. The only difference in the subject and predicate devices is the subject devices also have a commercially pure titanium coating. In addition, the predicate and subject devices are both convex, bullet-nosed interbody devices designed to contain graft material and facilitate a fusion between two vertebral bodies.

VIII. Identification of Legally Marketed Devices:

The CAPSTONE PTC™ Spinal System has the same indications for use and fundamental scientific technology as the predicate, CAPSTONE® Spinal System (K073291, SE 4/24/2008 and K123027, SE 07/25/2013). The CLYDESDALE PTC™ Spinal System has the same indications for use and fundamental scientific technology as the predicate, CLYDESDALE® Spinal System (K1130528, SE 12/20/2011 and K122037, SE 3/22/2013).
An additional predicate, Spinal Element's Lucent Ti-Bond Spinal System (K110632, SE 5/23/2012), is also being used to demonstrate that the commercially pure titanium coating is not new and currently exists on other legally marketed devices.

IX. Discussion of Non-Clinical Testing:

Testing of the plasma-sprayed coating was performed according to FDA's Guidance for FDA Reviewers/Staff, "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements," issued February 2, 2000. The testing was performed according to the applicable ASTM standards listed below:

Coating Microstructure:

- ASTM F1854, Standard test method for stereological evaluation of porous coatings on medical implants

Shear Fatigue Testing:

- ASTM F1160, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/ Metallic Coatings

Static Shear Testing:

- ASTM F1044, Standard test method for shear testing of calcium phosphate coatings and metallic coatings

Tensile Testing:

- ASTM F1147, Standard test method for tension testing of calcium phosphate & metallic coatings

Abrasion Testing:

- ASTM F1978, Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser

In order to demonstrate substantial equivalence to the predicate devices, mechanical testing was conducted. Static compression, dynamic compression, static compression shear, and dynamic compression shear fatigue testing were performed in accordance with ASTM F2077: Test Methods for Intervertebral

Body Fusion Devices. Subsidence testing was performed in accordance with ASTM F2267: Standard Test Method for Measuring Load Induced Subsidence of the Intervertebral Body Fusion Device under Static Axial Compression. Static push-out (expulsion) testing was also performed in accordance with ASTM Draft Standard F04.25.02.02, Static Push-out Test Method for Intervertebral Body Fusion Devices. In addition, wear particulate testing was performed in accordance with ASTM F1877, Standard Practice for Characterization of Particles.

Animal testing was also performed using canines and CP Ti coated coupons.

XI. Conclusion:

Based on the risk analysis, test results, and additional supporting documentation provided in this pre-market notification, Medtronic believes the subject CAPSTONE PTC™ and CLYDESDALE PTC™ Spinal Systems are substantially equivalent to the predicates, the CAPSTONE® and CLYDESDALE® Spinal Systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 13, 2014

Medtronic Sofamor Danek USA, Incorporated
Ms. Julie Bassett
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K133205
Trade/Device Name: CAPSTONE PTC™ Spinal System and CLYDESDALE PTC™ Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 17, 2014
Received: February 18, 2014

Dear Ms. Bassett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133205

Device Name

CAPSTONE PTC™ Spinal System

Indications for Use *(Describe)*

The CAPSTONE PTC™ Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the CAPSTONE PTC™ Spinal System is indicated to assist in the setting of spinal deformity as a supplement to pedicle screw fixation in patients diagnosed with degenerative scoliosis.

These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the Food and Drug Administration (FDA) for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

David Hwang, Ph.D.
Division of Orthopedic Devices

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133205

Device Name

CLYDESDALE PTC™ Spinal System

Indications for Use *(Describe)*

CLYDESDALE PTC™ Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and are intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE PTC™ Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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